

## **REMARKS**

### ***Summary of Office Action***

In the Office Action, the Examiner advised that should claims 1, 6 and/or 8 be found allowable, claims 11, 16 and/or 18 would be objected to under 37 CFR 1.75 as being substantial duplicates thereof. The Examiner also rejected claims 1, 6, 8, 11, 16 and 18 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,752,522 to Murphy (hereinafter “Murphy”). No other issues were presented.

### ***Summary of Amendments***

Upon entry of the present Amendment and Request for Continued Examination, Claims 1 and 11 will have been amended, and claim 30 will have been added. Claims 2-5, 7, 9-10, 12-15, 17 and 19-29 remain in withdrawn status. As such, Claims 1-30 remain currently pending. The amendments to claims 1 and 11 are supported at least by paragraphs [0014], [0029] and Figures 1, 3a and 3b of the originally filed specification. By the present amendment, Applicant submits that the rejections have been overcome and respectfully requests reconsideration of the outstanding Office Action.

### ***Applicant’s Response***

#### **1. Provisional Objection to Claims under 37 CFR 1.75**

The Examiner indicated that if claims 1, 6 and/or 8 were found allowable, that claims 11, 16 and/or 18 would be objected to under 37 CFR 1.75 as being substantial duplicates thereof (*see* Office Action pages 2-3). This provisional rejection is respectfully traversed.

Applicant notes that claim 11 and the claims depending therefrom, including claims 16 and 18, differ from claim 1 and claims 6 and 8 depending therefrom in that claim 11 recites a device for “determining the amount of pressure between a first anatomical structure and a

second anatomical structure" (emphasis added) where the device comprises a sensor "operative to measure the compressive force exerted between said first anatomical structure and said second anatomical structure, produce a signal representative of the compressive force and transmit said signal" (emphasis added) and a monitor that is "operative to provide a quantifiable indication of the compressive force between said first anatomical structure and said second anatomical structure" (emphasis added).

In contrast, claim 1 is drawn to a device for "determining the pressure exerted within an anatomical structure" (emphasis added), where the device comprises a sensor that is operative to "measure pressure exerted within said anatomical structure, produce a signal representative of the pressure exerted within said anatomical structure and transmit said signal" (emphasis added), and the device also comprises a monitor operative to "provide a quantifiable indication of the compressive force exerted within said anatomical structure" (emphasis added).

Thus, claim 11 differs from claim 1 in that it is directed to a device capable of measuring a pressure between two anatomical structures, and to that end the device has a sensor and a monitor that are suited to measuring this particular pressure, producing a signal representative of the pressure therebetween, and providing a quantifiable indication of the pressure. In contrast, the device of claim 1 determines the pressure exerted within an anatomical structure, and to that end the device has a sensor operative to measure the particular type of pressure and produce a signal representative of the pressure, and a monitor that provides a quantifiable indication of the particular type of pressure. Accordingly, claims 11 and 1 are not substantial duplicates of one another, and Applicant respectfully requests that the provisional objection to the claims be withdrawn.

2. Rejection of Claims 1, 6, 8, 11, 16 and 18 under 35 U.S.C. 102(b) over Murphy

The Examiner rejected claims 1, 6, 8, 11, 16 and 18 under 35 U.S.C. 102(b) as being anticipated by Murphy because the Examiner asserts that Murphy discloses an anatomical pressure-sensing device that meets the limitations of the claim, and in particular refers to column

9, lines 12-35 of Murphy (*see* Office Action pages 3-4). Applicant respectfully traverses this rejection.

Claim 1 as amended recites a device for determining pressure exerted within an anatomical structure comprising, *inter alia*, “a sensor comprising an encapsulated member having (i) a membrane enclosing an encapsulated volume therewithin and (ii) a body of supportive material disposed within the membrane that defines the encapsulated volume” (emphasis added), as recited in the claim. Murphy does not teach a sensor having a membrane and a body of supportive material within the membrane that defines the encapsulated volume of the membrane, and thus Murphy does not anticipate the sensor of claim 1.

Instead, Murphy teaches a catheter for determining the cross-sectional dimensions of body lumens, such as blood vessels (*see, e.g.*, Abstract), in which the measurement of a width of a catheter balloon gives an indication of the diameter of the lumen being measured (*see, e.g.*, column 7, line 66 through column 8, line 12). Murphy teaches that in one embodiment the catheter balloon has bands of conductive material (also called resistors 62) that can be formed of a polymer or elastomer material having conductive properties, such as polysiloxane foam with graphite impregnation (*see, e.g.*, column 9, lines 12-20 and Figures 5-6). Murphy shows the bands being disposed about a circumference of the balloon (*see, e.g.*, Figures 5-6), and describes how expansion or contraction of the balloon changes the electrical resistance of the bands, which can be measured to calculate the width of the balloon (*see, e.g.*, column 9, lines 21-35).

Thus, while Murphy teaches conductor bands added as sensors about a circumference of a balloon, Murphy does not teach the encapsulated member of claim 1 having the membrane and body of supportive material that defines the encapsulated volume enclosed by the membrane. The conductor bands of Murphy are merely strips of material disposed along the length of the catheter balloon to help in measuring the diameter of the balloon. Murphy does teach that these conductor bands somehow serve to define the encapsulated volume of the balloon. In fact, Murphy teaches that the balloon is “inflated,” for example using a fluid (*see, e.g.*, column 8, lines

12-50), and thus appears to teach that the internal volume of the balloon is defined by the fluid used to inflate the balloon, including presumably any air used to inflate the balloon. Murphy does not teach that structural elements or bodies of supportive materials are otherwise placed within the balloon to define its encapsulated volume, as in the instant claim.

It is furthermore noted that claim 1 is not obvious over the teachings of Murphy because Murphy does not teach or suggest the desirability of providing a body of supportive material within a membrane to define the encapsulated volume therein, as in the claim. As Murphy only teaches filling a balloon with fluid or air, and using conductor bands as sensing devices, one of ordinary skill in the art would have had no motivation to modify the teachings of Murphy to place the claimed body of supportive material within the balloon catheter. In contrast, Applicant has discovered that the body of supportive material placed within an encapsulated member membrane that defines the encapsulate volume provides advantages in measuring pressures between or within anatomical structures. For example, in the embodiment where the body of supportive material is compressive foam it can be understood that the body of supportive material allows for ready transitioning from an expansive state under reduced pressure to a compressed state under increased pressure, and back to the expansive state when the pressure is released (*see, e.g.*, claim 6), thereby allowing for multiple different measurements to be taken. In contrast, the balloon catheter of Murphy, once deflated, may not transition back to the expansive state without a positive pressure of air or fluid flowing back into the catheter (*see, e.g.*, Murphy's Figure 1).

Accordingly, claim 1 is not anticipated by or obvious over the teachings of Murphy, and the rejection of this claim and the claims depending therefrom is respectfully requested to be withdrawn.

Claim 11 similarly recites a device for determining a pressure having a sensor with "an encapsulated member having (i) a membrane comprising an encapsulated volume therewithin and (ii) a body of supportive material disposed within the membrane that defines the

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encapsulated volume,” and thus is not anticipated by or obvious over the teachings of Murphy for at least the same reasons as claim 1.

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### Conclusion

Applicant respectfully submits that each and every pending claim of the present invention meets the requirements for patentability under 35 U.S.C. §§ 102 and 37 CFR 1.75, and respectfully requests that the Examiner indicate allowance of each and every pending claim of the present invention. In view of the foregoing, it is submitted that none of the references of record, either taken alone or in any proper combination thereof, anticipate or render obvious Applicant's invention as recited in each of Claims 1, 6, 8, 11, 16, 18 and 30. The applied references of record have been discussed and distinguished, while significant claim features of the present invention have been pointed out.

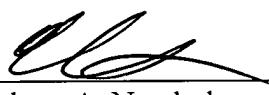
Accordingly, reconsideration of the outstanding Office Action and allowance of the present application and all the claims therein are respectfully requested and now believed to be appropriate. To the extent the Examiner has any questions, requires additional information and/or has any suggestions to resolve any outstanding issues that may exist, the Examiner is invited to contact Applicants' counsel at the number listed below.

If any additional fee is required, please charge Deposit Account Number 19-4330.

Respectfully submitted,

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